

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| |
|--|
| Date of mailing (day/month/year) 05 January 2001 (05.01.01) |
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| International application No. PCT/US00/08759 | Applicant's or agent's file reference |
| International filing date (day/month/year) 31 March 2000 (31.03.00) | Priority date (day/month/year) 02 April 1999 (02.04.99) |

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| Applicant HANNIGAN, Raymond, R. et al |
|--|

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

02 November 2000 (02.11.00)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|-------------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Pascal Piriou |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |

F. ~~INT COOPERATION TREA~~

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)Date of mailing (day/month/year)
19 December 2000 (19.12.00)

From the INTERNATIONAL BUREAU

To:

COLTON, Wayne, J.
Wayne J. Colton, Inc.
Suite 1032
The Milam Building
115 East Travis Street
San Antonio, TX 78205
ETATS-UNIS D'AMERIQUE

Applicant's or agent's file reference

IMPORTANT NOTIFICATION

International application No.
PCT/US00/08759International filing date (day/month/year)
31 March 2000 (31.03.00)

1. The following indications appeared on record concerning:

 the applicant the inventor the agent the common representative

Name and Address

COLTON, Wayne, J.
Wayne J. Colton, Inc.
Suite 1108
The Milam Building
115 East Travis Street
San Antonio, TX 78205
United States of America

State of Nationality State of Residence

Telephone No.

210 222 8455

Facsimile No.

210 222 8445

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

 the person the name the address the nationality the residence

Name and Address

COLTON, Wayne, J.
Wayne J. Colton, Inc.
Suite 1032
The Milam Building
115 East Travis Street
San Antonio, TX 78205
United States of America

State of Nationality State of Residence

Telephone No.

210 222 8455

Facsimile No.

210 222 8445

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

 the receiving Office
 the International Searching Authority
 the International Preliminary Examining Authority the designated Offices concerned
 the elected Offices concerned
 other:The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Dominique DELMAS

Telephone No.: (41-22) 338.83.38

003732108

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: WAYNE J. COLTON
WAYNE J. COLTON, INC.
115 EAST TRAVIS STREET
THE MILAM BUILDING SUITE 1032
SAN ANTONIO, TEXAS 78205

PCT

**NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

30 JUL 2002

Applicant's or agent's file reference

1001.1153

IMPORTANT NOTIFICATION

| | | |
|-------------------------------|--|--------------------------------|
| International application No. | International filing date (day/month/year) | Priority Date (day/month/year) |
| PCT/US00/08759 | 31 MARCH 2000 | 02 APRIL 1999 |
| Applicant | KINETIC CONCEPTS, INC. | |

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

| | |
|--|---|
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 | Authorized officer KIM M. LEWIS <i>Diane Smith</i> Telephone No. (703) 308-1191 |
|--|---|

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

| | | |
|---|---|---|
| Applicant's or agent's file reference 1001.1158 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US00/08759 | International filing date (day/month/year) 31 MARCH 2000 | Priority date (day/month/year) 02 APRIL 1999 |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61F 7/00 and US Cl.: 604/291 | | |
| Applicant KINETIC CONCEPTS, INC. | | |

| |
|---|
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |
|---|

| | |
|--|---|
| Date of submission of the demand 02 NOVEMBER 2000 | Date of completion of this report 19 MAY 2002 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 | Authorized officer KIM M. LEWIS <i>Diane Smith Jr.</i> Telephone No. (703) 308-1191 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/08759

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:pages 1-6 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____ the claims:pages 7-8 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____ the drawings:pages 1 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____ the sequence listing part of the description:pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in printed form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages NONE

the claims, Nos. NONE

the drawings, sheets/fig NONE

5. This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/08759

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | | |
|-------------------------------|--------|------|-----|
| Novelty (N) | Claims | 7-10 | YES |
| | Claims | 1-6 | NO |
| Inventive Step (IS) | Claims | 7-10 | YES |
| | Claims | 1-6 | NO |
| Industrial Applicability (IA) | Claims | 1-10 | YES |
| | Claims | NONE | NO |

2. citations and explanations (Rule 70.7)

Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,149,331 ("Ferdman et al.").

Claims 1-6, Ferdman et al. disclose a method and device for wound closure. More specifically, Ferdman et al. disclose an adhesive backed dressing in which a vacuum and/or heat is applied to the wound through the dressing in order to close the wound and minimize trauma. It should be noted that cooling of the affected region occurs when the heat and vacuum are removed.

Claims 7-10 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest packing the wound site with a foam pad, the foam pad being in fluid communication with vacuum source, sealing the region, including the foam pad with a wound drape and communication the vacuum from the vacuum source through the foam pad to the region.

----- NEW CITATIONS -----

NONE

WORLD TRADE ORGANIZATION
WTO COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|---|--|
| Applicant's or agent's file reference 1001.1153 | FOR FURTHER ACTION | see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |
| International application No. PCT/US00/08759 | International filing date (day/month/year) 31 MARCH 2000 | (Earliest) Priority Date (day/month/year) 02 APRIL 1999 |
| Applicant KINETIC CONCEPTS, INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. **Certain claims were found unsearchable** (See Box I).

3. **Unity of invention is lacking** (See Box II).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

as suggested by the applicant.

None of the figures.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

NEW ABSTRACT

A method, and apparatus (10) for the controlled acceleration, and/or retardation of the body's inflammatory response generally comprises a foam pad (11) for insertion substantially into a wound site, a heating, a cooling pad (13) for application over the wound site (12), a wound drape (14) or sealing enclosure of the foam pad (11), the heating, and cooling pad (13) at wound site (12). The foam pad (11) is placed in fluid communication with a vacuum source for promotion of the controlled acceleration or retardation of the body's inflammatory response. The heating, and cooling provision controls the local metabolic function as part of the inflammatory response.

VACUUM ASSISTED CLOSURE SYSTEM
WITH HEATING AND COOLING PROVISION

RELATED APPLICATION:

5 This application claims priority to United States provisional patent application Serial No. 60/127,596 entitled VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION filed April 2, 1999. By this reference, the full disclosure, including the drawings, of U.S. provisional patent application Serial No. 60/127,596 is incorporated herein.

10

TECHNICAL FIELD:

15 The present invention relates to the healing of wounds. More specifically, the present invention relates to the vacuum assisted closure of wounds wherein localized heating or cooling is used to accelerate or retard the metabolic function of the inflammatory system in order to facilitate wound healing.

BACKGROUND ART:

20 Wound closure involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the 25 tissues) forms near the surface of the wound.

30 Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until recently, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can 35 eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not repairable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable 5 with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been 10 developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative pressure, commonly referred to as vacuum assisted closure (VAC) therapy, typically involves mechanical-like contraction of the 15 wound with simultaneous removal of excess fluid. In this manner, VAC therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While VAC therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. 20 Because the inflammatory process is very unique to the individual patient, even the addition of VAC therapy does not result in a fast enough response for closure of some wounds, especially when applied during the occlusion and initial cleanup and rebuilding stages. It is therefore a principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through controlled acceleration of 25 the inflammatory response.

Additionally, and again at least partially attributable to the variance between patients, it is possible that a properly initiated inflammatory response may be taken too far, resulting in edema and pain. It is therefore another principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through 30 controlled retardation of the inflammatory response.

DISCLOSURE OF THE INVENTION:

In accordance with the foregoing objects, the present invention – a method and apparatus for the controlled acceleration and/or retardation of the body's inflammatory 35 response – generally comprises a foam pad for insertion substantially into a wound site, a

heating and cooling pad for application over the wound site and a wound drape for sealing enclosure of the foam pad and the heating and cooling pad at the wound site. According to the invention, the foam pad is placed in fluid communication with a vacuum source for promotion of fluid drainage while warm or cool fluid is circulated through the heating and 5 cooling pad for the controlled acceleration or retardation, respectively, of the metabolic function portion of the body's inflammatory response.

According to the preferred embodiment of the present invention, a heating and cooling provision is added to the previously known VAC therapy to control the local metabolic function as part of the inflammatory response. By providing localized heating in 10 combination with the otherwise ordinary VAC therapy, the overall inflammatory response can be synergistically accelerated to produce rapid capillary occlusion and earlier initiation of the cleanup and rebuilding stages. Likewise, in the event that the attending clinician determines that the inflammatory response has been over-activated, localized cooling may be provided in combination with the VAC therapy to retard the body's inflammatory response 15 without sacrifice of the edema control and other aspects of the otherwise provided VAC therapy.

In the preferred embodiment of the present invention, the heating and cooling pad comprises a flexible and breathable water layer, generally comprising two sheets of RF-weldable material. The two sheets of the pad are RF-welded together in a waffle-like pattern, 20 wherein a plurality of apertures is formed between a plurality of channels. The apertures allow the transpiration of moisture from the patient's skin while the channels allow the circulation, via a supply tube and a drainage tube, of warm or cool water, as required, through the pad for the heating or cooling thereof.

While the heating and cooling pad may be placed inside or outside of the wound 25 drape during the heating aspect of the present invention, it is critical that the heating and cooling pad be placed inside of the wound drape during the cooling aspect of the present invention. In this manner, condensate formation on the interior of the drape, which may cause the drape's adhesive to loosen and ultimately result in loss of vacuum at the wound site, can be minimized. In particular, placing the heating and cooling pad inside the wound drape 30 limits the surrounding moisture content to that existing and generated within the confines of the wound site, which is minimized by the suction aspect of the VAC therapy.

Because the cooling aspect of the present invention should be implemented in this manner and the clinician may indicate the need for cooling at any time after initiation of VAC therapy, the preferred method of the present invention comprises placing the heating 35 and cooling pad beneath the wound drape, adjacent the foam pad and wound site, regardless

of whether heating or cooling is initially indicated. Upon placement of the pad, the wound drape is firmly adhered about the supply tube and drainage tube to prevent vacuum leakage.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing 5 discussions, the following drawings and exemplary detailed description and the claims appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS:

Although the scope of the present invention is much broader than any particular 10 embodiment, a detailed description of the preferred embodiment follows together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

Figure 1 shows, in partially cut away perspective view, the preferred embodiment of the present invention as applied to a mammalian wound site; and

Figure 2 shows, in top cross-sectional plan view, the heating and cooling pad of the 15 invention of Figure 1.

BEST MODE FOR CARRYING OUT THE INVENTION:

Although those of ordinary skill in the art will readily recognize many alternative 20 embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention – a vacuum assisted closure system with heating and cooling provision, the scope of which is limited only by the claims appended hereto.

Referring now to the figures, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into a wound site 12, a heating and cooling pad 13 25 for application over the wound site 12 and a wound drape 14 for sealing enclosure of the foam pad 11 and the heating and cooling pad 13 at the wound site 12. According to the invention, the foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage while warm or cool fluid is circulated through the heating and cooling pad 13 for the controlled acceleration or retardation, respectively, of the metabolic 30 function portion of the body's inflammatory response.

According to the preferred embodiment of the present invention, the foam pad 11, wound drape 14 and vacuum source are implemented as known in the prior art, each of which is detailed in U.S. patent application Serial No. 08/517,901 filed August 22, 1995. By this 35 reference, the full disclosure of U.S. patent application Serial No. 08/517,901 ("the '901 application"), including the claims and the drawings, is incorporated herein as though now

set forth in its entirety. Additionally, such a VAC system is readily commercially available through Kinetic Concepts, Inc. of San Antonio, Texas, U.S.A. and/or its subsidiary companies.

As detailed in the '901 application, the foam pad 11 preferably comprises a highly 5 reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction. As also detailed in the '901 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 15, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump. 10 Finally, the '901 application also details the wound drape 14, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '901 application are generally employed as known in the art with the 15 exception that the heating and cooling provision of the present invention is added to control the local metabolic function as part of the inflammatory response. By providing localized heating in combination with the otherwise ordinary VAC therapy, the overall inflammatory response can be synergistically accelerated to produce rapid capillary occlusion and earlier initiation of the cleanup and rebuilding stages. Likewise, in the event that the attending 20 clinician determines that the inflammatory response has been over-activated, localized cooling may be provided in combination with the VAC therapy to retard the body's inflammatory response without sacrifice of the edema control and other aspects of the otherwise provided VAC therapy.

In the preferred embodiment of the present invention, the heating and cooling pad 13 25 comprises a flexible and breathable water layer 16, generally comprising two sheets 17, 18 of RF-weldable material. The two sheets 17, 18 of the pad are RF-welded together in a waffle-like pattern, wherein a plurality of apertures 19 is formed between a plurality of channels 20. The apertures 19 allow the transpiration of moisture from the patient's skin 21 while the channels 20 allow the circulation, via a supply tube 22 and a drainage tube 23, of warm or 30 cool water, as required, through the pad 13 for the heating or cooling thereof.

While the heating and cooling pad 13 may be placed inside or outside of the wound drape 14 during the heating aspect of the present invention, it is critical that the heating and cooling pad 13 be placed inside of the wound drape 14 during the cooling aspect of the present invention. In this manner, condensate formation on the interior and near the edges of 35 the drape 14, which may cause the drape's adhesive to loosen and ultimately result in loss of

vacuum at the wound site 12, can be minimized. In particular, placing the heating and cooling pad 13 inside the wound drape 14 limits the surrounding moisture content to that moisture level existing and generated within the confines of the wound site 12, which is minimized by the suction aspect of the VAC therapy.

5 Because the cooling aspect of the present invention should be implemented in this manner and the clinician may indicate the need for cooling at any time after initiation of VAC therapy, the preferred method of the present invention comprises placing the heating and cooling pad 13 beneath the wound drape 14, adjacent the foam pad 11 and wound site 12, regardless of whether heating or cooling is initially indicated. Upon placement of the pad 13, 10 the wound drape 14 is firmly adhered about the supply tube 22 and the drainage tube 23 to prevent vacuum leakage.

While the foregoing description is exemplary of the preferred embodiment of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, 15 especially in light of this description, the accompanying drawings and the claims drawn hereto. For example, those of ordinary skill in the art will recognize that the heating and cooling pad 13 may be constructed in a wide variety of shapes, sizes and internal structures. Such an alternative embodiment may comprise the integration of the heating and cooling pad 13 into a multi-layered version of the wound drape 14. In any case, because the scope of the 20 present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the present invention, which is limited only by the claims appended hereto.

INDUSTRIAL APPLICABILITY:

25 The present invention is applicable to the wound healing arts.

CLAIMS:

What is claimed is:

1. A method for the promoting wound healing in mammals, said method comprising the
5 steps of:
 - applying a vacuum to a region of a wound site on a mammal; and
 - effecting a change in the mammal's inflammatory response at said region while said vacuum is applied thereto.
- 10 2. The method for promoting wound healing as recited in claim 1, wherein said effecting a change step comprises controlling the mammal's local metabolic function at said region.
- 15 3. The method for promoting wound healing as recited in claim 2, wherein said effecting a change step comprises accelerating the mammal's local metabolic function at said region to encourage rapid capillary occlusion and accelerated initiation of the cleanup and rebuilding stages of the mammal's inflammatory response.
- 20 4. The method for promoting wound healing as recited in claim 3, wherein said effecting a change step comprises heating said region.
- 25 5. The method for promoting wound healing as recited in claim 2, wherein said effecting a change step comprises retarding the mammal's local metabolic function as said region to prevent over-activation of the mammal's inflammatory response.
6. The method for promoting wound healing as recited in claim 5, wherein said effecting a change step comprises cooling said region.
- 30 7. The method for promoting wound healing as recited in any of the preceding claims, wherein said applying a vacuum step comprises the steps of:
 - packing said wound site with a foam pad, said foam pad being in fluid communication with a vacuum source;
 - sealing said region, including said foam pad, with a wound drape; and
 - communicating said vacuum from said vacuum source through said foam pad to said region.

8. The method for promoting wound healing as recited in claim 7, wherein said effecting a change step comprises the steps of:
circulating a fluid about said region; and
controlling the temperature of said fluid to obtain said change.

5

9. The method for promoting wound healing as recited in claim 8, wherein said fluid is circulated about said region in a flexible envelope, said flexible envelope having an inlet and an outlet for fluid communication therethrough of said fluid.

10. 10. The method for promoting wound healing as recited in claim 9, said method further comprising the step of sealing said flexible envelope, with said wound drape, between said foam pad and said wound drape.

1/1

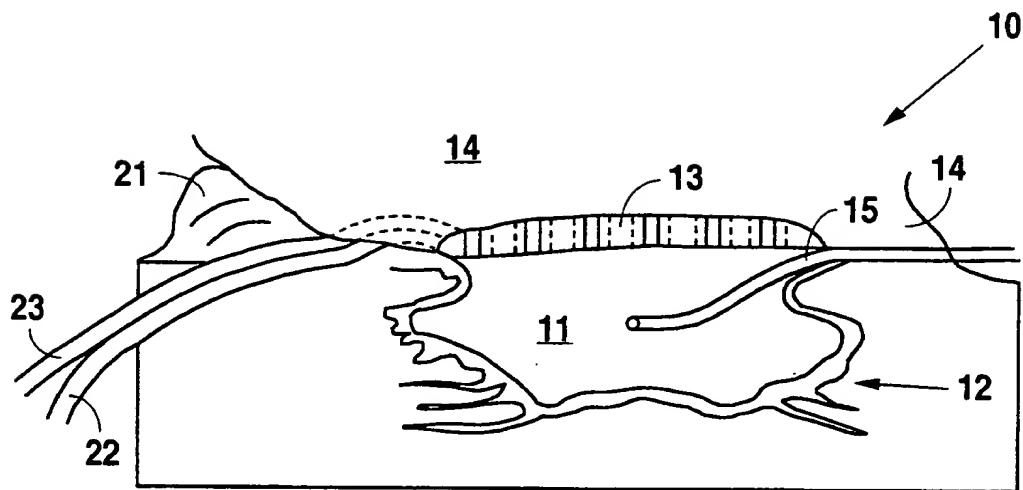


Fig. 1

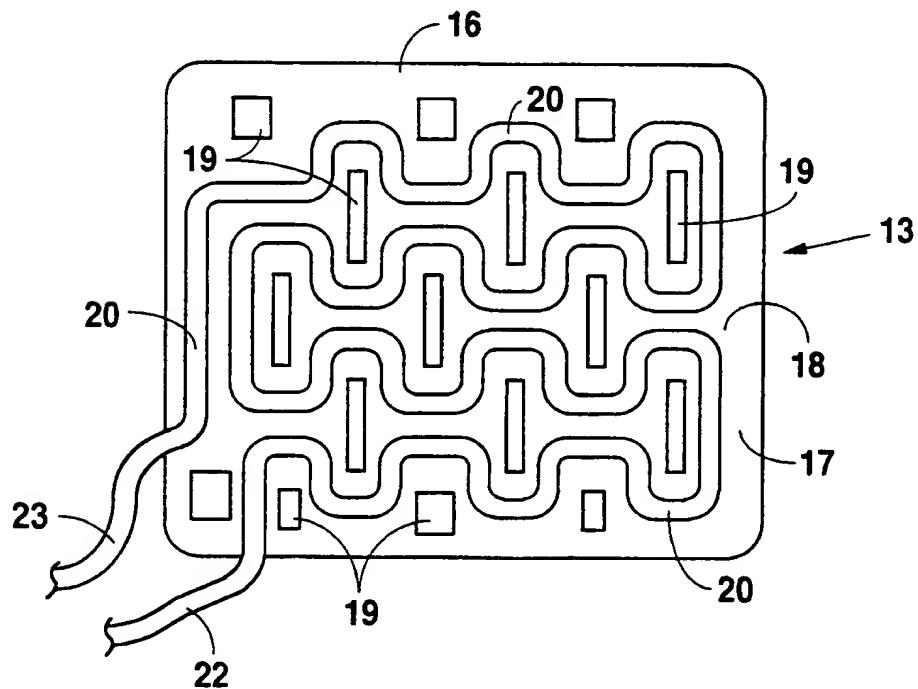


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/08759

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 7/00
US CL : 604/291

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/290, 291

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

Search Terms: bandage, dressing, vacuum, pad, heating, cooling, inflammatory

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | US 5,149,331 A (FERDMAN et al.) 22 September 1992, entire document. | 1-6 |
| --- | | ----- |
| Y | US 4,382, 441 A (SVEDMAN) 10 May 1983, entire document. | 7-10 |

 Further documents are listed in the continuation of Box C. See patent family annex.

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Date of the actual completion of the international search

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